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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,860	03/31/2005	Hiromu Ohnogi	1422-0670PUS1	1481

2292 7590 07/13/2006

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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/529,860	OHNOGI ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae.

Group II, claims 5 and 6, drawn to a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae.

Group III, claims 7 and 8, drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a compound represented by the following formula (A): a derivative thereof or a salt thereof.

Group IV, claim 9, drawn to a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises the compound represented by the formula (A) as defined in claim 7, a derivative thereof or a salt thereof.

Group V, claim 10, drawn to a method for measuring an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b)

measuring an amount of BMP in a culture medium obtained in the step (a) as an index for an enhancing action for BMP production of the test substance.

Group VI, claim 11, drawn to a method for screening a substance having an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a) wherein the test substance is determined to have an enhancing action for BMP production when the amount of BMP is larger than that of a case where the cells are cultured without contact of the test substance or with contact of a control substance having an enhancing action for BMP production.

Group VII, claim 12, drawn to a method for preparing a substance having an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) obtaining a substance having an enhancing action for bone morphogenetic protein production; and (b) measuring the enhancing action for bone morphogenetic protein production of the substance obtained in the step (a) using the measurement method as defined in claim 10.

Group VIII, claim 13, drawn to a method for preparing a substance having an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a), wherein the test substance is determined to have an enhancing action for BMP production when the amount of BMP is larger than that of a case where the cells are cultured without contact of the test substance or with contact of a control substance having an enhancing action for BMP production, thereby giving the test substance as a substance having an enhancing action for BMP production.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from

a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae, whereas the special technical feature of Group II is drawn to a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae and a search for a therapeutic agent is not required for a search for a food, beverage or feed. The special technical feature of Group III is drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a compound represented by the following formula (A): a derivative thereof or a salt thereof and the special technical feature of Group IV is drawn to a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises the compound represented by the formula (A) as defined in claim 7, a derivative thereof or a salt thereof, and neither Group III nor Group IV require the particulars of Group I since Group I requires an effective ingredient a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a

plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae, whereas Groups III and IV require a compound represented by the following formula (A): a derivative thereof or a salt thereof and a search for a plant product is not co-extensive with a search for a compound represented by the following formula (A): a derivative thereof or a salt thereof. The special technical feature of Groups V and IV are drawn to unrelated methods of use, where in the special technical feature of Group V is drawn to a method for measuring an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a) as an index for an enhancing action for BMP production of the test substance and the special technical feature of Group VI is drawn to a method for measuring an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a) as an index for an enhancing action for BMP production of the test substance. A search for the special technical feature of Group I is not required for a search for the special technical feature of Groups V and VI, since the inventions are unrelated. Finally, the special technical feature of Groups VII and VIII are drawn to method of preparing a substance having enhancing action and a search for the special technical feature of

Group I is not required for Groups VII and VIII since the methods of Groups VII and VIII are unrelated to the agent of Group I. Finally, Claim 1, at least, is anticipated by or obvious over Ishino et al. (JP 11-269044, 05.10.1999). Ishino teaches a therapeutic agent consisting of an extract of Compositae gnaphalium. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so the invention lacks unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
The species are as follows:

Group I:

Specie A: elect one plant from Claims 1 and 3.

Further elect the corresponding specific plant specie from Claims 2 and 4 that is specific to the elected plant family from Claim 1. For example, if Umbelliferae is elected as Specie A, further elect Angelica keiskei koidz. as the plant from Claim 2.

Group II:

Specie A: elect the compound, derivative or salt from Claim 7.

Group III:

Specie A: elect the compound, derivative or salt from Claim 9.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I:
Specie A: drawn to Claims 2 and 4.
Group II:
Specie A: drawn to Claim 6.
Group III:
Specie A: drawn to Claim 8.
Group IV:
Specie A: drawn to Claim 9.

The following claims are generic: Claims 1, 3 and 5.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are independent or distinct because the plant families listed in Claims 1, 3 and 5, the plant species listed in Claims 2, 4 and 6 and the compound, derivatives of the compound and salts of the compound listed Claim 7 are distinct both physically and functionally from each other both within each Claim and between the Claims. And a search for one plant family, one plant specie and a compound is not co-extensive with a search for another.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy L. Clark
AU 1655

Amy L. Clark
July 3, 2006

MICHELE FLOOD
PRIMARY EXAMINER